formulations which do not contain particles of above specified diameter limits or preferably the volume weighted mean particle diameter of the suspension does not increase after steam sterilization by more than about two-times.

Replace the paragraph beginning at page 3, line 20 with:

While the surface modifiers possibly adsorb to the freshly made surfaces of drug particles during the process of particle size reduction, and (a) convert the lipophilic drug surface to a hydrophilic surface that has increased stability, and (b) possibly modify the surface charge of the drug particle surfaces, the thermoprotecting agent and thermoprotecting conditions described herein help maintain the particle size distribution of the suspension during and after the terminal steam sterilization conditions.

IN THE CLAIMS:

Replace the indicated claims with:

21. (Amended) An autoclavable composition of an aqueous injectable terminally steam sterilized suspension in a vial sealed under nitrogen atmosphere, said suspension containing particles of a water insoluble or poorly soluble biologically active substance with a volume weighted mean particle size of up to 3 μm, said particles surface stabilized with one or more phospholipid surface modifiers, and a pharmaceutically acceptable amount safe for parenteral administration of a pharmaceutically acceptable, water soluble polyhydroxy thermoprotecting agent selected from the group consisting of trehalose, lactose, dextrose, sorbitol, dextran, mannitol and mixtures thereof, the ratio of said active substance to said surface modifier is 1:1 to 5:1, and the amount of said surface modifier is in the range from 0.2% w/w to 5.0% w/w, wherein said composition is substantially completely devoid of surfactants that require during terminal steam sterilization elevation of their cloud point temperature by addition of a cloud point modifier, said composition is substantially devoid of surfactant additives which coagulate on steam sterilization, and said volume weighted mean particle size is not increased more than two-fold during and after terminal steam sterilization.

22. (Amended) An autoclavable composition of an injectable non-flocculating aqueous terminally steam sterilized suspension under nitrogen in a sealed vial, said suspension containing particles of a water insoluble or poorly soluble drug substance with a volume weighted mean particle size of up to 3 μm, said particles surface stabilized with one or more phospholipid surface modifiers, and a pharmaceutically acceptable amount safe for parenteral administration of a pharmaceutically acceptable, water soluble polyhydroxy thermoprotecting